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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,200	12/05/2001	Michael R. Wessels	B00801/70237 (ERG/MXA)	8283

7590 05/05/2004

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,200	WESSELS ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4 February 2004* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *See Continuation Sheet* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19,21-23,45 and 68* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1-19,21-23,45,68,91,115,139-141,143,145-147,149,151-153,155,157-159 and 161.
Continuation of Disposition of Claims: Claims withdrawn from consideration are 91,115,139-143,145-147,149,151-153,155,157-159 and 161.

FINAL ACTION

1. This Office Action is responsive to Applicant's response filed February 4, 2004.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

Objection/Rejection Withdrawn

3.

a) In view of Applicant's submission of amended Formal Drawings the objection to the drawings is withdrawn.

b) In view of Applicant amendment and response the rejection of claims 1-19, 21-23, 45 and 68 under 35 U.S.C. 103(a), pages 3-4, paragraph 4 of the previous Office Action is withdrawn.

c) In view of Applicant amendment and response the rejection of claims 1-19, 21-23, 45 and 68 under 35 U.S.C. 103(a), pages 6-7, paragraph 6 of the previous Office Action is withdrawn.

Rejections Maintained

4. The rejection of claims 1-19, 21-23, 45 and 68 under 35 U.S.C. 112, second paragraph is maintained for the reasons set forth on page 2, paragraph 2 of he previous Office Action.

The rejection was on the grounds that the claims recite the term "reduce the likelihood". It is unclear as to what the applicant is referring? Thus, the metes and bounds of "reduce the likelihood" cannot be ascertained. Clarification as to the meaning of this term is required.

Applicant urges that the phrase "reduce the likelihood" is clear when read in the context of the specification.

Applicant's arguments filed February 4, 2004 have been fully considered but they are not persuasive. The specification does not define the phrase "reduce the likelihood". The specification merely teaches that a statistically significant reduction in the likelihood of infection may be determined. The specification does not describe how this determination is made. Therefore, the rejection is maintained.

5. The rejection of claims 1-19, 21-23, 45 and 68 under 35 U.S.C. 103 (a) unpatentable over Schrager et al is maintained for the reasons set forth on pages 4-6, paragraph 5 of the previous Office Action.

The rejection was on the grounds that Schrager et al teach that the monoclonal antibody to CD44, IM7.8.1 blocked attachment not only to stains that produced measurable amounts of capsule but also to strains that produced very low amounts of capsule (page 1715, 1st column). Schrager et al teach a method of treating a subject to reduce the likelihood of streptococcal or staphylococcal infections wherein the treatment is free of Echinacea. Claim limitations such as dosage requirements, time periods and

number of administrations are being viewed as limitations of optimizing experimental parameters".

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to use the IM7.8.1 antibody as taught by Schrager et al in the method of treating against streptococcal and staphylococcal infections because Schrager et al teach that the monoclonal antibody to CD44, IM7.8.1 blocked attachment not only stains that produced measurable amounts of capsule but also strains that produced very low amounts of capsule (page 1715, 1st column), thereby preventing the adhesion of bacteria to the CD44 protein in the subject and inhibiting bacterial colonization of the pharynx. It would be expected barring evidence to the contrary, that the IM7.8.1 antibody would be effective in a method of treating against streptococcal and staphylococcal infections because the IM7.8.1 antibody prevents colonization of the pharynx .

Applicant urges that Schrager et al do not teach or suggest every claim limitation. Applicant urges that Schrager et al discloses the application of a monoclonal antibody, IM7.8.1 to CD44 in cultured cells and does not disclose administration of the antibody to a subject. Applicant urges that *in vitro* methods are not simply transferable to *in vivo* applications. Applicant urges that an antibody that inhibits binding of some strains of streptococcal bacteria to CD44 *in vitro* would not provide one of ordinary skill in the art with a reasonable expectation that the oral administration of antibody would prevent streptococcal or staphylococcal infection in a subject.

Applicant's arguments filed February 4, 2004 have been fully considered but they are not persuasive. Schrager et al teach that the monoclonal antibody to CD44, IM7.8.1 blocked attachment of strains that produced measurable amounts of capsule as well as strains that produced very low amounts of capsule (page 1715, 1st column), thereby preventing the adhesion of bacteria to the CD44 protein and inhibiting bacterial colonization of the pharynx. It should be noted that claim limitations such as dosage requirements, time periods and number of administrations are being viewed as

limitations of optimizing experimental parameters". The Examiner agrees with Applicant's statement that "*in vitro* methods are not simply transferable to *in vivo* applications". However, Schrager et al teach that the hyaluronic acid capsule may function as a universal adhesion for most GAS strains associated with human infection permitting attachment of the bacteria to epithelial cells by a mechanism that is independent of strain or serotype-specific expression of alternative ligands (page 1715). Schrager et al also teach the cellular receptor for the GAS capsule CD44 is a transmembrane glycoprotein expressed on the surface of many epithelial, mesenchymal and hematopoietic cells. Schrager et al teach that in studies of the human tonsils it was found that CD44 expressed both on the epithelial surface of the tonsillar crypts and on the pharyngeal aspect of the tonsils (page 1715). Therefore, one of ordinary skill in art would reasonably expect that if attachment of bacteria is blocked by IM7.8.1, streptococcal and staphylococcal infections would be prevented in human patients. In response to applicant's argument that the Examiner has not established a *prima facie* case of obviousness, the Examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Status of Claims

7. No claims are allowed.

NITA MINNIFIELD
PRIMARY EXAMINER

Conclusion

8. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Vanessa L. Ford
Biotechnology Patent Examiner
April 27, 2004

NITA MINNIFIELD
PRIMARY EXAMINER
5/3/04